

REMARKS

According to the Official Action, the Abstract contains a minor typographical error. The Abstract has now been amended to correct this error.

Claims 8-15 were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. This rejection, which is set forth in numbered paragraph 5 on pages 2-3 of the Official Action, is respectfully traversed.

The Official Action has noted certain inconsistencies in Claim language between Claims 8, 10, 12 and 14 and Claim 1, from which these claims depend. Accordingly, Claims 1, 8, 10, 12 and 14 have been amended as set forth above. It is respectfully submitted that these amendments obviate the rejection of Claims 8-15 under 35 U.S.C. §112.

Claims 8, 10, 12 and 14 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,338,532 to Tomalia et al. (hereinafter referred to as "Tomalia") in view of various references discussed in the specification. This rejection is set forth in numbered paragraph 7 on pages 3-4 of the Official Action. Claims 8-15 have also been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tomalia in view of the references discussed in the specification and further in view of Simons, Bioconjugate Chemistry (1999), vol. 10, pp. 3-8. This rejection is set forth in numbered paragraph 8 on pages 2-3 of the Official Action. Each of the above rejections is respectfully traversed.

Each of the above rejections relies upon the combination of Tomalia and the references discussed in the "Background" section of the specification. The Official Action seems to acknowledge that neither Tomalia nor these other references specifically disclose a chemiluminescent substrate delivery system as set forth in Claims 8-15 comprising a dendrimer and a chemiluminescent enzyme substrate. Moreover, in order to arrive at the invention defined by Claims 8-15, the Official Action combines Tomalia's generalized teachings of dendrimer

conjugates with the teachings of these other references which are related generally to chemiluminescent enzyme substrates.

It is respectfully submitted that the Official Action has failed to establish a *prima facie* case of obviousness. First, in order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Further, the teaching or suggestion to make the claimed combination must be found in the prior art and not in the Applicants' disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143. According to the MPEP, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP § 2143.01. The Official Action, however, has pointed to no teaching or suggestion in any of the cited references which would lead one of ordinary skill in the art to combine the reference teachings in the manner proposed in the Official Action. The Official Action instead relies upon the disclosure in Tomalia of conjugates of dendrimers and “optically detectable moieties” (pg. 3 of the Official Action). Tomalia does in fact broadly disclose “signal generators” (i.e., “fluorescing moieties”) associated with dendrimers (Column 7, Lines 13-17 of Tomalia). This disclosure of “signal generators”, however, is included amongst a laundry list of possible choices for the dendrimer coupled material. Moreover, Tomalia also discloses dendrimers coupled to a wide variety of other unrelated materials, including pharmaceuticals, pesticides, radionuclides, chelants, toxins, antibodies, and antigens (Column 7, Lines 13-17 of Tomalia). Further, the class of potential “signal generators” is nearly limitless in number. As defined by Tomalia, this class of materials includes “. . . anything that results in a detectable and measurable perturbation of the system due to its presence” (Column 8, Lines 32-34 of Tomalia). Interestingly, although numerous examples

of "signal generators" are disclosed in Tomalia, chemiluminescent moieties are not among them. Since the Official Action has pointed to no teaching in Tomalia or any other reference which would suggest the choice of chemiluminescent moieties in general, much less enzymatically activatable chemiluminescent substrates as set forth in Claims 8-15, it is respectfully submitted that the Official Action has failed to establish a *prima facie* case of obviousness.

In view of the above, reconsideration and withdrawal of the rejection of Claims 8-15 is respectfully requested.

CONCLUSION

Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants' counsel, Christopher W. Raimund at (202) 326-0253.

Respectfully submitted,

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